GOVERNOR'S OFFICE OF HEALTH POLICY & FINANCE

CHAPTER 101-2: CAPITAL INVESTMENT FUND FOR MAINE'S CERTIFICATE OF NEED PROGRAM

BASIS STATEMENT

The Governor's Office of Health Policy and Finance has determined that immediate adoption of this rule is necessary to avoid an immediate threat to the public health, safety and general welfare of the people of Maine. In making this determination the following considerations have been taken:

- **A one-year limitation on Certificate of Need (CON) review expired on May 5, 2004.** On June 21, 2004 the Certificate of Need Unit of the Department of Health and Human Services issued a notice of pending Certificate of Need activity. That notice provided the first public statement of Certificate of Need activity subsequent to the expiration of the CON limitation implemented on May 5, 2003. By May 17, 2004, less than two weeks following the expiration of the limitation, there were eleven Letters of Intent on file with the Certificate of Need Unit for reviewable projects.[1] These projects include: a proposal to expand MRI services at an estimated cost of $1.8 million submitted by NEHE-MRI, LLC; Mercy Hospital's Phase II proposal for the replacement of its current facility, at an estimated cost of $90 million; a proposal for a facility expansion at Southern Maine Medical Center at an estimated cost of $30 million; a proposal for a construction/renovation project at an estimated cost of $20 million from York Hospital; a proposal for the construction of a $26 million ambulatory surgical center at Maine Medical Center; a proposal to develop a 12-bed Cardiac Care Unit for $3.8 million at Eastern Maine Medical Center; and a proposal to acquire Blue Hill Hospital submitted by Eastern Maine HealthCare (no estimate of costs provided). In June 2004, four additional Letters of Intent were submitted. These Letters outlined the following contemplated proposals: a proposal to develop an ambulatory surgical center by US HealthWorks (no estimated cost provided); a $17 million construction/renovation project at Inland Hospital; a $2.3 million project to relocate and expand cardiac catheterization and angioplasty services at Central Maine Medical Center; and a $23 million project to develop a regional cancer center by MaineGeneral Medical Center. Taken together, these projects propose the expenditure of more than $200 million in new costs into Maine's health care system.

- **This level of activity is higher than usual.** On average, the Certificate of Need Unit addresses 35 Letters of Intent each year.[2] The pace exhibited in the first eight weeks following the expiration of the CON limitation is 67% above the usual volume of activity in terms of the numbers of Letters submitted. The high number of Letters of Intent submitted may, in fact, be attributable to "pent up demand" within the hospital industry, as the one-year CON limitation precluded the submission of proposals. However, the dollar values reflected in the filed Letters are already considerably higher as well. In 1998, the CON Unit approved $81 million in capital costs. This figure dropped during the period 1999-2001, with approved capital costs totaling $46 million in 1999, $41 million in 2000 and $49 million in 2001. In 2002, $100 million in capital costs were approved.[3] The cost estimates included in the currently filed Letters of Intent (more than $200 million) are well above that most recent level, *indicating the potential for extraordinarily high costs being infused into our health care system.*

- **These projects are in addition to those currently under review, which total an estimated $103 million in total costs.** Further, costs associated with Certificate of Need projects represent only a fraction of the total investments made by health care providers.[4] For example, in 2002, CON projects represented only 20% of total capital expenditures made by hospitals, the balance of investments falling outside the purview of the CON program. It is reasonable to estimate, then, that the total value

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[1] Monthly Update of Certificate of Need Activities, 2004. Issued by DHHS Certificate of Need Unit, July 1, 2004.
[2] Personal correspondence, William Perfetto, Director, Certificate of Need Unit, DHHS. July 19, 2004.
[3] *ibid*
[4] Nancy Kane, DBA. Maine Hospital Financial Performance: 1993-2002. Presentation to Commission to Study Maine's Community Hospitals, June 21, 2004.

of capital investment currently "in the pipeline" is $1.07 billion[5] for both projects reviewable under Maine's Certificate of Need program as well as projects that do not require such review. Controlling even 20% of this level of investment represents a critical tool in managing our state's health care costs.

- **The high cost of health care continues to be an immediate threat to the general welfare of thousands of Maine residents.** Health care spending in Maine in 1998 was an estimated $5 billion,[6] or 15.5% of the gross state product.[7] By 2004, spending is estimated to increase to $7.7 billion,[8] or 17.9% of gross state product.[9] Health insurance premiums for Maine's businesses rose 77% between 1996 and 2002.[10]

  Premium increases continued to rise at double-digit levels in 2003, with the national rate of increase reaching 13.9%. While this represents a moderation in the rate of growth, this rate outpaced the overall inflation rate (2.2%) and the rate of change in workers' earnings (3.1%).[11] At the same time, the trend in coverage has been toward higher out of pocket payments for insurance enrollees in the form of increasing copayments,[12] deductibles and payment of a growing proportion of the premium itself, when that cost is shared with an employer.[13]

  Between 1991 and 1998 (the last year for which 50-state estimates are available), Maine's per capita health care spending increased faster than all other states in the nation, at an average rate of 7.3%.[14] The average rates of growth for New England and the nation over this same time period were 5.5% and 4.9% respectively.[15] Because of Maine's fast rate of increase, Maine went from being 31st highest in per capita health care spending in 1991 to 11th highest in 1998.[16]

  Health care spending is growing faster than our ability to pay for it. Growth in health care spending exceeded growth in income in all but two of the 13 years from 1992 to 2004, with health care spending increasing by an average of 6.9% per year,[17] while income increased by only 4.2% per year.[18] The overall result of these increases is that between 1991 and 2004 personal health care spending increased by 137%, while income has increased by only 70%.[19]

- **As the cost of care goes up, so does the number of uninsured and underinsured.** Spiraling costs hamper adequate access to health care for many Mainers. Approximately 136,000 non-elderly Maine residents are uninsured and 189,000 spend at least part of the year without coverage.[20] Most

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[5] ($214 million/20%)
[6] Computed using data from US Census Bureau. www.cms.hhs.gov/statistics/nhe/state-estimates-residence/us-per-capita10.asp. Inflation adjustments taken from www.cms.hhs.gov/statistics/nhe/projections-2003/t2.asp.
[7] Computed using data provided by Maine State Planning Office
[8] *op cit* at 6
[9] *op cit* at 7
[10] Agency for Healthcare Quality and Research, USDHHS. www.meps.ahrq.gov/Data_Pub/IC_Tables.thm
[11] *Trends and Indicators in the Changing Health Care Marketplace, 2004 Update.* Kaiser Family Foundation, at http://www.kff.org/insurance/7031/index.cfm.
[12] *ibid*
[13] Employer Health Benefits: 2003 Summary of Findings. The Kaiser Family Foundation & Health Research and Educational Trust. Publ. No. 3369.
[14] Center for Medicare and Medicaid Services, USDHHS. www.cms.hhs.gov/statistics/nhe/state-estimates-residence/us-per-capita10.asp
[15] *ibid*
[16] *ibid*
[17] Computed usingInflation adjustments taken from www.cms.hhs.gov/statistics/nhe/projections-2003/t2.asp
[18] US Census Bureau, Current Population Surveys. www.census.gov/hhes/www/previnc.html
[19] Reflects actual changes in current year dollars, without adjustments for inflation
[20] Ziller E and Kilbreth E. Health Insurance Coverage Among Maine Residents: The Results of a Household Survey, 2002. Institute for Health Policy, Edmund S. Muskie School of Public Service, University of Southern Maine. May 2003.

of the uninsured (80%) work and two-thirds of the working uninsured have full time employment.[21] Maine's very small businesses – those with fewer than 10 workers – employ about 20% of all workers, but this group represents more than 40% of the uninsured in our state.[22] And more than half of the uninsured live in families with household income below 200% of the federal poverty guidelines.[23]

- **A lack of coverage has definite and serious implications on access to health care.** As noted in the Maine Health Access Foundation's *Primer on Health Care Coverage in Maine*,[24] the impact of being uninsured is profound. Uninsured women, for example, are far less likely than insured women to have a mammogram and uninsured women diagnosed with breast cancer have a 49% greater chance of dying from their disease. Risk of premature death among the uninsured is more than 20% greater than that for insured individuals. The Institute of Medicine has estimated that 18,000 people between the ages of 25 and 64 die each year as a consequence of being uninsured, making it the sixth leading cause of death in this country.[25]

  The uninsured receive fewer preventive services, tend to be diagnosed at more advanced stages of disease and, once diagnosed, receive less treatment and suffer poorer outcomes of care – including higher mortality rates – than do people with insurance coverage.[26] In Maine, uninsured adults are three times as likely as insured adults to delay necessary care and more than 40% of families with uninsured children delay needed care for those children due to costs – a rate seven times that observed in insured families.[27] These children may lose the opportunity for normal development and full educational achievement due to preventable health conditions.[28]

  When the uninsured do seek care, it is at a later stage in the disease process, when the condition is more complex and requires more complicated and often much more costly intervention. A recent study by the national Center for Studying Health System Change finds that many Americans – 43 million people – reported having problems paying their medical bills in 2003, with uninsured families having the most difficulty.[29] Almost all persons reporting difficulty paying for medical bills also cite difficulty paying for other basic necessities including housing costs, food and transportation.[30] Having problems paying medical bills compounds the challenge of accessing care; for example, almost half of uninsured individuals in families having such difficulties report not getting prescription drugs they needed.[31] Finally, medical bills are responsible for almost one-half of all personal bankruptcies in this country.[32]

- **Lack of coverage impacts all of us, not just the uninsured.** The uninsured generate costs that are experienced by each resident of Maine. Most obvious is the impact on the uninsured themselves, outlined above. Further, individuals who are uninsured have lower earnings, arising at least in part, from reduced participation in the workforce due to poor health and lower productivity.[33] Productivity losses hold obvious implications for employers, who must pass along these costs in the form of

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[21] *ibid*
[22] *ibid*
[23] *ibid*
[24] *op cit* at 2
[25] Davis K. The Costs and Consequences of Being Uninsured. *Medical Care Research and Review.* 60(2): 89S-99S. June 2003.
[26] Access to Care for the Uninsured: An Update. The Kaiser Commission on Medicaid and the Uninsured. The Henry J. Kaiser Family Foundation. September 2003.
[27] *op cit* at 10
[28] *Hidden Costs, Value Lost: Uninsurance in America.* Institute of Medicine.
[29] May JH and Cunningham PJ. Tough Trade-offs: Medical Bills, Family Finances and Access to Care. Center for Studying Health System Change. Issue Brief No. 85. June 2004. *See* http://www.hschange.com/CONTENT/689/?topic=topic01
[30] *ibid*
[31] *ibid*
[32] *ibid*
[33] *op cit* at 15

higher prices, potentially compromising their competitive position. This is a statewide issue that affects our tax base, gross state product and the fiscal viability of our economic future.

The health system itself feels the effect of the uninsured. It is estimated that there is nearly $275 million in bad debt and charity care each year in Maine's health care system. These costs threaten the viability of our hospitals, clinics, pharmacies, physicians and other providers, putting access to services at risk for all Mainers.[34] To a large extent, this represents expenses incurred by people without adequate insurance coverage and without the ability to pay the out of pocket costs for their care. Health care providers attempt to recover the costs associated with this care by raising the price of care paid by insured individuals. This is the source of the $275 million "hidden tax" mentioned above.

There are also hidden costs associated with a failure to deliver adequate and timely care to our residents. Contagious diseases can go untreated if an uninsured person is unable to access care, thereby threatening the health of entire communities. Further, as mentioned earlier, the strain of caring for the un- and underinsured can serve to compromise the financial integrity of our health care system compromising access to needed services for all of us.

- **The Maine Certificate of Need Program is designed to help control health care costs.** As stated in the Certificate of Need Act, this purpose reflects findings by the Legislature that "unnecessary construction or modification of health care facilities and duplication of health services are substantial factors in the cost of health care and the ability of the public to obtain necessary medical services."[35]

  The Dirigo Health Reform Act, PL 469, revised the CON statute in an effort to enhance the cost containment tools available to state government. The revised statute extends applicability of the CON statute beyond the traditional facility or hospital campus and now includes both multi- and single specialty surgical centers, even when they are located within the office of a health care provider. When the original law was crafted, the most costly and technologically advanced services were provided by hospitals. Over time, these services have migrated first to the outpatient hospital setting, then to free standing diagnostic and surgical facilities. Now the development of very sophisticated and costly services in even office based settings is relatively common. In extending the purview of the CON statute, the Dirigo Health Reform Act filled a gap in policymakers' ability to carefully consider and direct the rational development of Maine's healthcare system, as well as allowing us to assess the impact on systems costs represented by such investments.

  In enacting these statutory changes, the Legislature was cognizant of the impact new health care projects will have on the continuing ability of Mainers to access and afford health care services. The statutory provisions of the Dirigo Health Reform Act reflect that concern by establishing the Capital Investment Fund (CIF), which serves as an annual limit on new CON approved expenditures and is one of several tools enacted as part of the Dirigo Health Reform Act to reduce the growth in Maine's health care costs.

  The statute, at 2 MRSA chapter 5, section 102, directs the Governor to conduct rulemaking to establish a process for determining the funding level each year for the CIF; these process rules are designated as major, substantive regulations. The Governor has named the Director of his Office of Health Policy and Finance as his designee to carry out duties – including any necessary rulemaking – related to establishment of the Capital Investment Fund.[36] The statute requires the Governor's Advisory Council on Health Systems Development to conduct at least two public hearings on the capital investment fund each biennium.[37] While the statute does not explicitly reference a requirement of the Council to hold public hearings on the *process* of establishing the Capital Investment Fund – the subject of the rulemaking considered here – that process leads directly to the value of the Fund in any given year. Therefore, the public hearings to be held by the Council would relate specifically to that process.

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[34] *Dirigo Health: Health Reform for Maine.* Governor's Office of Health Policy and Finance. May 2003.
[35] 22 MRSA 327(1)
[36] Letter from John E. Baldacci to Trish Riley, May 28, 2004.
[37] 2 MRSA c.5 §104(7)(C)

The Council is also charged with advising the Governor on the development of the State Health Plan which, in part, must set out the priorities for capital investment needs of Maine's health care system especially as they relate to the Capital Investment Fund.[38] The Council is further directed by the statute to conduct at least 2 public hearings each biennium on the State Health Plan.[39]

Due to an oversight by the Secretary of State, the Advisory Council was only officially sworn in on January 16th of this year. The Advisory Council did hold a number of meetings during the early months of the year. At the January 16th meeting, they discussed a very early draft of a rule designed to govern the Capital Investment Fund, to which they suggested revisions to be considered at a later meeting. The Council also met on February 3rd at which time they worked to establish a plan to address the many tasks assigned to them; they also began to consider the issue of a statewide health expenditure "budget" for Maine. The Council met on March 5th to hear from a national expert on the issue of evaluating statewide health expenditure budgets. These early meetings were primarily focused on building a working relationship among members and identifying strategies to carry out their many statutory responsibilities. The early meetings were also used to build the knowledge base required to address the task of providing meaningful advice regarding the development of the first State Health Plan. The Council began to address the Plan itself in a very focused manner in mid-May, 2004, holding a hearing on a draft Plan on June 4, in Augusta.

Even if the Council had signed off on a draft rule at its first substantive meeting, the APA process for major substantive rules precluded submission of a provisionally adopted rule to the Legislature by the statutory deadline of 75 days prior to the adjournment date.[40] Furthermore, this schedule failed to allow adequate time for the Council to convene a public hearing on the process proposed by the rule in a timely fashion. More importantly, the Council lacked the time to address the development of a meaningful State Health Plan, which is intimately tied, by statute, to the Capital Investment Fund. There was no possibility for presenting the rule in a timely fashion to the Legislature for consideration during that session. Instead, the Governor's Office went forward with rulemaking beginning on June 7, 2004 to adopt a provisional rule assuming the rule would be reviewed during the session convening January 2005. This meant that the rule would likely not be finally adopted until late spring or early summer of 2005, well after the current $200 million worth of Letters of Intent before the Department of Health and Human Services completed the CON review process.

On June 29, 2004, the Governor's Office held a public hearing on the proposed rule, designated as chapter 101, Establishment of the Capital Investment Fund. At that hearing, comments were offered by representatives of the payer and business communities, as well as consumers and providers. A number of those comments on the proposed rule are reflected in this rule, as evidenced by the Response to Comments being filed today. A variety of commenters representing payers, business and consumers strongly urged the Governor's Office to move to emergency rulemaking to allow the capital investment fund to be put into effect immediately. One representative of a major health system offered a similar comment, pushing for adoption of the rule as soon as possible, so as to minimize the level of uncertainty facing providers who might wish to undertake a major capital project. The comments advocating emergency rulemaking noted that Maine people and business can no longer sustain the rising costs of health care in this state. They strongly suggested that the people of Maine cannot wait for the Legislature to sanction adoption of the rule, citing rising health care costs and anything exacerbating those costs – such as a delay in limiting investment in new capital projects – as an unacceptable threat.

Later that same day, the Advisory Council on Health Systems Development held its own hearing on the capital investment fund. After considering the comments made on the proposed rule by interested parties, the Council also came to the conclusion that a delay in the final adoption of the rule would result in harm to the public by failing to provide any relief in cost increases associated with new capital investments.

[38] 2 MRSA c. 5 §104(7) and §103(3)(D)
[39] *op cit* at 32
[40] 5 MRSA chapter 375, subchapter 2-A, §8072(7)

- **Immediate adoption of this rule is necessary to exercise legislatively mandated control over the level of capital investment to be approved over the coming months.** Despite the fact that Certificate of Need regulates only a portion of the total capital investments made in Maine's health care system in any single year, the significant level of funding being requested at the current time far exceeds the capacity of Maine's people to pay for it. It will contribute to increased costs of care, increases in premiums and a resulting decline in coverage. As outlined above, this spiral leads to poorer health status, a need for more costly health care interventions and poorer outcomes of the care provided, along with a loss of productivity. Immediate adoption of this rule will allow for the implementation of a limitation on the level of regulated investment that may be made in any given year. This limitation was called for by the Legislature in the Dirigo Health Reform Act, and the process set forth in this rule will be before the Legislature for its review in its next session. This rule will help contain health care costs and help protect access to coverage and needed services, guarding the welfare of the people of the state of Maine.

- **Therefore, in light of:**
    - The immediate need to implement additional limits on new capital investments, including the $200 million worth of projects pending before the Department of Health and Human Services in order to alleviate the dangers identified above;
    - The determination of the Legislature that the Certificate of Need Act is intended to address the problem of high health care costs caused by the unnecessary construction or modification of health care facilities and the duplication of health services;
    - The determination of the Legislature that the implementation of the Capital Investment Fund is necessary to enhance the cost containment value of the Certificate of Need Program;
    - The inability of the Legislature to act on this rule until late spring or early summer 2005;
    - The input of members of the public – including consumers, business, payers and providers – during formal rulemaking proceedings urging the emergency adoption of this rule;
    - The advice of the Advisory Committee on Health Systems Development recommending emergency adoption of the rule; and
    - The immediate threat presented to the welfare of the people of Maine by high health care costs,

This rule has been promulgated by the Governor's Office of Health Policy & Finance.

STATUTORY AUTHORITY
2 MRSA c. 5, §101, §§1, paragraph (D)
2 MRSA c.5, §105
5 MRSA c. 375, §8054

EMERGENCY EFFECTIVE DATE
July 26, 2004 through July 26, 2005